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08/908,469 APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY. DOCKET NO.

08/06/97 08/06/97 BACA M P1093P1

EXAMINER

HM21/0831

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LINCAR, S. ART UNIT PAPER NUMBER

1642  
1642

DATE MAILED: 08/31/98

This is a communication from the examiner in charge of your application.  
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### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 7/13/98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-42 is/are pending in the application.  
Of the above, claim(s) 1-33 + 39-42 is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 34 - 38 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). 4  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 1642

1. The Election filed July 13, 1998 (Paper No. 7) in response to the Office Action of June 9, 1998 (Paper No. 6) is acknowledged and has been entered. Claims 1-42 are pending in the application and Claims 1-33 and 39-42 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 34-38 are currently under prosecution.
2. The response (Paper No. 7) to the restriction requirement of June 9, 1998 has been received. Applicant has elected Group II, claims 34-38 without traverse.

***Specification***

3. The specification on page 1 should be amended to reflect the status of the parent application serial number 08/833,504.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

5. Claims 34-38 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 94/10202.

The claims are drawn to an isolated nucleic acid encoding a humanized anti-VEGF antibody which binds human VEGF with a  $k_d$  value of no more than about  $1 \times 10^{-8}M$ , a vector comprising the nucleic acid, a host cell comprising the vector and a process of producing a humanized anti-VEGF antibody comprising culturing the host cell so that the nucleic acid is expressed.

WO94/10202 teaches the preparation of anti-VEGF monoclonal antibodies with  $k_d$ s of  $1.2 \times 10^{-9}M$  and  $2.5 \times 10^{-9}M$  (see pgs 18-20, especially p.20 lines 21-24) and further teaches that after hybridoma cells are identified that produce VEGF antagonist antibodies the DNA encoding the monoclonal antibodies of the invention is readily isolated and sequenced using conventional procedures and once isolated, the DNA may be placed into expression vectors which are then transfected into host cells to obtain the synthesis of monoclonal antibodies in the recombinant host cells and further teaches that the DNA may be humanized by various techniques and will preferably have an affinity for immunizing antigen of at least about  $1 \times 10^{-9}M$  (see p.

7, line 32 through p. 8 line 35). WO94/10202 discloses as set forth above, but does not disclose an isolated nucleic acid encoding a humanized anti-VEGF antibody which binds human VEGF with a  $k_d$  value of no more than about 1  $\times 10^{-8}$  M, a vector comprising the nucleic acid, a host cell comprising the vector and a process of producing a humanized anti-VEGF antibody comprising culturing the host cell so that the nucleic acid is expressed.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one of ordinary skill in the art would have been motivated to produce an isolated nucleic acid encoding a humanized anti-VEGF antibody which binds human VEGF with a  $k_d$  value of no more than about 1  $\times 10^{-8}$  M, a vector comprising the nucleic acid, a host cell comprising the vector and a process of producing a humanized anti-VEGF antibody comprising culturing the host cell so that the nucleic acid is expressed in view of the explicit suggestions disclosed on page 8 of the reference.

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4242.

Art Unit: 1642

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to [lila.feisee@uspto.gov](mailto:lila.feisee@uspto.gov).

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

August 27, 1998



LILA FEISEE  
SUPERVISORY PATENT EXAMINER